

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Invention I (claims 62-82, 84-86, 89-95 and 97-99) made with traverse in the reply filed on 10/41/2009, has been acknowledged. Accordingly, claims 83, 87-88, 96 and 100-105 have been withdrawn as being directed to non-elected inventions.

The traversal is on the grounds that the statement that establishes the lack of unity of the inventions, as presented in the 08/14/2009 Office Action, is incorrect because 'it is premature to make any discussion regarding what features contribute to novelty to the claims'. Examiner notes that the 08/14/2009 Office Action, in addition to the statement per se, also presents an evidence to support the statement that the only technical feature common for the inventions in question (that is a reactor comprising a region that accommodates a probe-ligand moiety) does not contribute any novelty over the prior art. In particular, Applicants were referred to Figure 1 of Schembri et al., US 6258593, showing reactor 1, 3 which includes substrate region 2 upon which probe ligands are arrays, as is also disclosed in Col. 11, lines 5 plus). Based on at least this evidence, Examiner maintains that the unity of inventions is lacking. Since the searches for the invention identified in the 08/14/2009 Office Action, would not overlap and would require different search strategies, reasoning and search terms, the examination of the non-elected inventions would impose an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the convex flow-path, the protective unit and the blank region, as well as the open partition-structure comprising a substrate blank region and a convex, where the substrate blank region and substrate probe region are on the same plane of a same substrate, must be clearly shown and referenced, or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62-82, 84-86, 89-95 and 97-99 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite ranges for several parameters (namely, for height, thickness, distance and time), each range being followed by a corresponding optimal range. For example, claim 62 recites in line 7 the "height of 1-1000 microns, optimally 1-500 microns". All such recitations are unclear because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

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Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 62 includes the broad recitation of the height in the range of 1-1000 microns, and the claim also includes the recitation of the optimal height in the range of 1-500 microns, which is the narrower statement of the range/limitation. The same consideration applies to claims 64-67, 71, 80, 83, 85, 89 and 95. Additionally, it is not clear whether or not the substrate recited in line 30 of claim 62, is the same as the top or the bottom unit of line 22. Regarding the recitation of the 'striped capillary reaction chamber', it is not clear from the claim language what structural features of the chamber define it as a 'striped capillary' one. The claim also recites a 'closed partition structure. It is unclear, whether or not a cover for closing the partition structure is intended.

In claim 63, 'said convex' lacks antecedent basis. It is also unclear what structural features of the convex are defined by the recited methods of its making.

In claims 70 and 89, "said ligand" lacks antecedent basis.

In claim 87 'the open partition structure' lacks antecedent basis.

In claim 88, the "marking-containing convex that does not cover the probe-ligand", is unclear because "convex" refers to a "protruding structure", as defined in the specification, while "probe-ligand" refers to a material capable of being immobilized.

It is also noted that the instant claims are formatted so that the main structural components recited in the claim body are numbered. Such numbering interferes with the numbering of paragraphs in the wherein clauses, as well as with the numbering of the claims themselves, which makes the claims hard to read. Examiner would like to recommend the use of different types of characters (such as letters from the Latin and / or Greek alphabets) for denoting different categories of items.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 62-68, 70-82, 84-86, 89-95 and 97-99 are rejected under 35 U.S.C. 102(b) as anticipated by Columbus (US 4323536).

Columbus discloses a multi-analyte test device comprising, as shown in Figures 1-2, reactor 10 which defines at least one reaction chamber formed by plane members 12, 14 ['top and bottom planes or units'] and side members 20 ['closed partition structure']. The device further includes test elements 30, 32, 34 and 36 made of hydrophilic materials, each test element contains reagents necessary for detection of analytes present in the test liquid ['substrate probe region accommodating probe-ligand(s)'], apertures 46, 50 ['inlet, outlet'] and boss 22 nor occupied by the test elements, the

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central area of the boss not being covered by the top member 14 ['substrate blank region', 'open partition structure']. Regarding the claimed size ranges for the planes, closed partition structure and substrate blank region, Figure 2 shows distance 's' which is sized 'between about 25 microns and about 500 microns' (Col.3, lines 41-42).

Columbus also teaches that 'preferred materials for members 12, 14 and 20 are non-fibrous plastics that are substantially impervious to aqueous liquids. Examples include acetates, polystyrene, polyethylene, ABS plastic and polycarbonate'(Col.5, lines 45-50). The listed materials are conventional substrate materials having, as shown above, low water-absorptivity and hydrophobicity, as claimed. In this connection, the walls of the central aperture 46 read on the 'hydrophobic convex', defined in the instant disclosure as 'protruding structure whose height is more than 0 in relation to the plane of the substrate.' Note that the optional and alternative features (such as absorbing or hydrophilic convex, reactor protecting structure, etc., are not positively recited as a part of the claimed invention, and, therefore, they are not accorded patentable weight. Similarly, it is noted regarding claim 70, that since ligands and ligates are not positively recited, they are not accorded any patentable weight.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus

Although Columbus does not disclose top member 14 being made of glass, it would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed a glass cover in the modified devices of Columbus, since glass is a conventional, chemically inert and inexpensive substrate material, such transparent cover would also facilitate visual monitoring of the test procedures.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Natalia Levkovich/

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